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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,415

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EXAMINER

MERENE, JAN CHRISTOP L

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

01/04/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,415	Applicant(s) PETRINI ET AL.	
	Examiner JAN CHRISTOPHER MERENE	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-29 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/25/2009 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This is Office action based on the 10/568,415 application which is a 371 National Stage Entry of PCT/IT04/00148 filed March 24, 2004, which also claims Foreign Priority to IT FI2003 A 000084 filed March 28, 2003.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 20-23, 27, 29, 31** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 recites the limitation "said anchoring plate" in line 2. Claim 21 recites the limitation "three projections" in line 2, where it is unclear if these are the same "shaped projections" recited in Claim 20. Claim 29 There are insufficient antecedent basis for these limitations in the claim.

Claim 27 recite "at each end of the elastic body has a said groove," where the statement is indefinite and unclear because it appears that the elastic body is part of the plate. Also, it is unclear if the applicant is reciting another set of grooves or the same groove as recited in claim 26. Since the applicant recited "said groove," the examiner will assume that the applicant meant to recite the same grooves in claim 26.

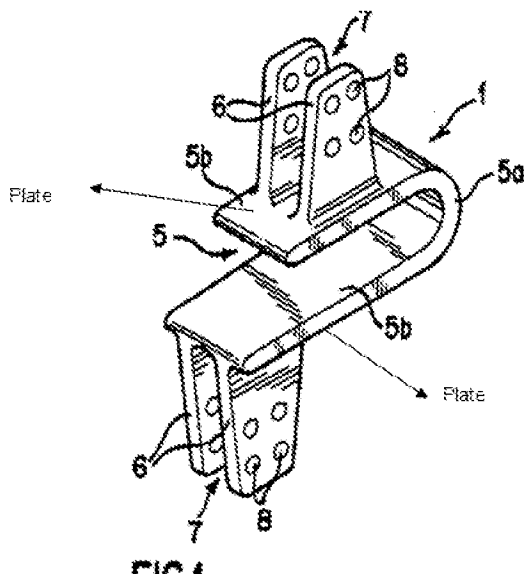
Claim Rejections - 35 USC § 102

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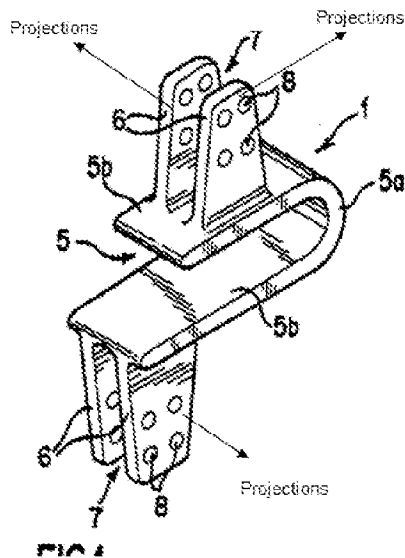
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. **Claims 17-23** are rejected under 35 U.S.C. 102(b) as being anticipated by Samani US 5,645,599.

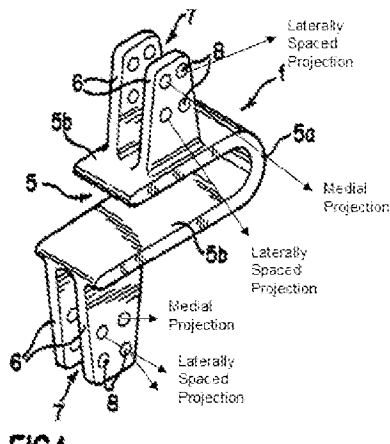
Regarding **Claim 17-19**, Samani discloses an intervertebral prosthesis comprising an elastic body (#5), securing means in the form of a plate, where the plate has outer surfaces, respectfully, that has engaging means which can engage the vertebra, where the plate is substantially rigid (as seen in Fig below and see Col 3 lines 37-41, where the body #5 is elastic and Col 3 lines 43-44, where the plate is substantially rigid, where the prosthesis would be capable of being inserted into the interlaminar region if one chooses to do so).



Regarding **Claims 20-21**, Samani discloses an anchoring plate with three projections (as seen in Fig below).



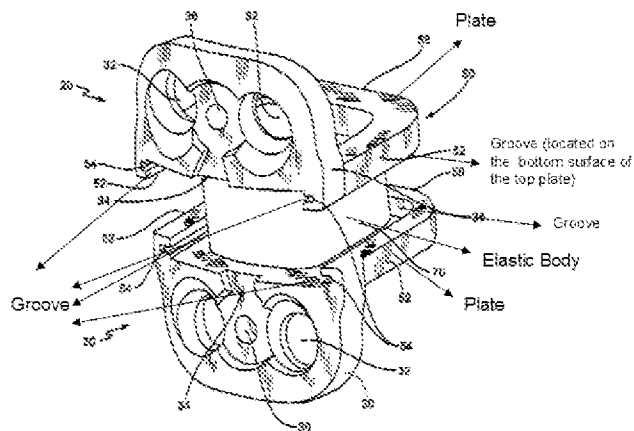
Regarding **Claims 20, 22-23**, Samani discloses an anchoring plate with two laterally spaced apart projections and a median projection (as seen in Fig below and Col 3 lines 54-58, where the holes #8 are for projections/screws), where the median projection is sufficiently thin/thick that it would not compress the spinal cord (see Fig below and Col 3 lines 54-58, where projection would engage bone not compress the spinal cord).



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7. **Claims 17-19, 26-27** are rejected under 35 U.S.C. 102(b) as being anticipated by Coates et al US 2004/0068318.

Coates discloses an intervertebral prosthesis comprising an elastic body, means for securing the elastic body via anchoring plates with engaging means, the outer surfaces of the plates, where the plates are rigid and where the plates have a surface groove, where the grooves are parallel to each other (as seen in Fig below and see paragraph 14, 19, where the body is elastic and see paragraph 17 where the plates are rigid).

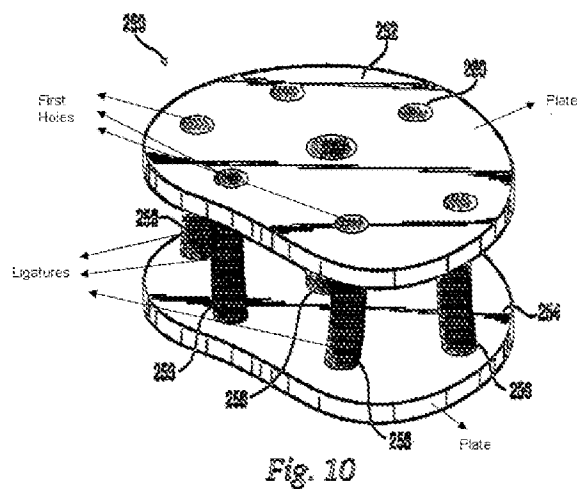


8. **Claims 17-19, 24-25** are rejected under 35 U.S.C. 102(e) as being anticipated by Coppes et al US 2005/0197702.

Coppes discloses an interverbral prosthesis comprising an elastic body, means for securing the elastic body via anchoring plates, where the plates are rigid, where the plates have engaging means with an outer surface to engage the vertebra, and connections means, including ligatures, passing through each through a first hole in the

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plates and a second hole in the elastic body (as seen in Fig below and see paragraph 92, where the elastic membrane/body is discussed but not shown in the Fig below, where the ligatures would pass through second holes in the elastic body, and see Fig below, where only the first holes are shown in one plate, where the other plate would also have corresponding first holes for the ligatures).



Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

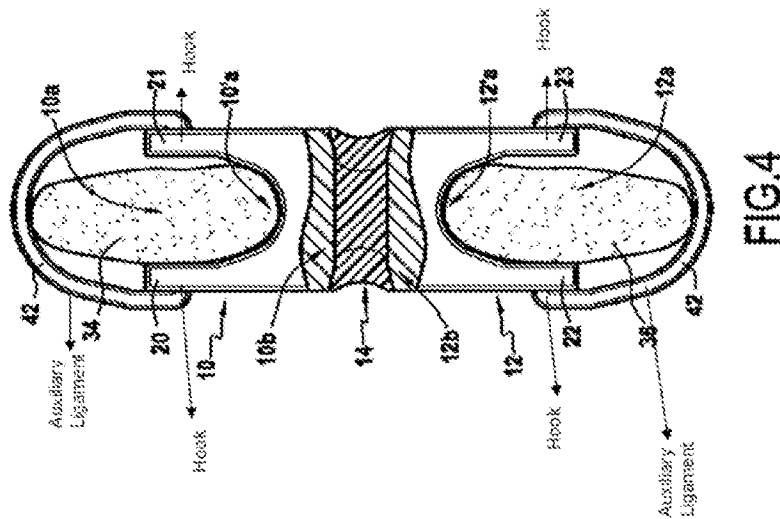
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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. **Claims 28-29, 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Samani US 5,645,599 in view of Le Couedic et al WO/2002/003882 (reference is made to US 2004/0106995, which is the English equivalent to LeCouedic et al) and Senegas WO/2001/28442 (reference is made to US 6,761,720 which is the English equivalent to Senegas).

Samani discloses the claimed invention as disclosed above, where the plate includes at least one engaging means, a hook (#8) for engagement with bone via bone screws (see Col 3 lines 55-57) but does not specifically disclose the hooks are used for engaging an auxiliary ligament.

However, Le Couedic teaches the use of anchors as well as auxiliary ligaments to secure and implant in place (see Fig below and see also Fig 3, where anchors are used).



However, Senegas discloses a similar device with the use of a single auxiliary element (#4" as seen in Figs 3-4) also used to help secure the prosthesis and where the prosthesis can simultaneously be tightened around the bone (see Col 3 lines 54-58).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the prosthesis of Samani to use an auxiliary ligament instead of bone anchors to secure the prosthesis in view of Le Coudedic because it is a simple substitution of one known type of anchoring element for another to obtain predictable results of securing an implant in place (see paragraph 52). It would have also been obvious to one having ordinary skill in the art to modify the combination of Samani and Le Coudedic to use a use a single auxiliary element in view of Senegas because it applies a known technique to a known device ready for improvement to yield predictable results of securing an implant around bone, where the prosthesis can simultaneously be tightened around the bone.

Response to Arguments

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12. Applicant's arguments filed September 25, 2009 have been fully considered but they are not persuasive. In response to applicant's argument that Samani is used for the spinous process and can not be considered a prosthesis, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The device of Samani can be placed in the inter laminar region if one chooses to do so. Likewise, the applicant argues that Coates and Coppes are not adapted for engaging the lumbar but that the prosthesis of Coates and Coppes can be placed in the interlaminar region if one chooses to do so. With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Samani which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

13. In response to applicant's arguments against the references individually regarding LeCoudic and Senegas, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As stated above, the device of Samani can

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be placed in the interlaminar region, wherein LeCoudic and Senegas teaches the use of auxiliary elements to secure a prosthesis (see above). The applicant is welcomed to contact the examiner to discuss any outstanding issues.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733